APR 1 8 2003

EXHIBIT 2. 510(K) SUMMARY

Jeil Medical Corporation
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Seoul, KOREA
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January 30, 2002

Contact: N.K.Kim, R&D Director

510(k) Summary

1. Identification of the Device:
   Proprietary-Trade Name: Leforte System Bone Screw
   Classification Name: Screw, Fixation, Bone, Product Code HWC
   Common/Usual Name: Bone Screw

2. Equivalent legally marketed device: Twist off™ Screw Medinov-AMP, K971069, Aesculap Titanium Alloy Bone Screws Aesculp, Inc., K970549, K3 Bone Screw System, Kinetikos Medical Inc., K960533

3. Indications for Use (intended use) . The Leforte System Screws are intended for fracture fixation as well as reconstruction and stabilization of small bones (i.e. toe, foot, finger, hand, etc) and the mandibulofacial (i.e. mandible and maxilla) bones

4. Description of the Device: Leforte system bone screw is made of Titanium alloy (ASTM F136) and consists of common bone screw, self-drilling screw (auto screw) and dual head screw. The common bone screws are classified to 4 classes; Micro screw, Mid screw, Mini screw, Maxi screw. This device is manufactured and intended for small bone (toe, foot, finger, hand etc.) and mandibulofacial (mandible & Maxilla) fracture fixation. Also This device is intended for reconstruction & stabilization of small bone and mandibulofacial (mandible & Maxilla) Jeil Medical Corporation utilizes the state of the art technology and apply the essential requirement of MDD (93/42/EEC) and ISO 14630, 1997 from the device design to manufacturing and QC...

5. Potential Adverse Affects and Complications: (Common to all devices of this type)

- Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device or premature loss of fixation with the bone, leading to nonunion.
- Nonunion or delayed union which may lead to breakage of the implant.
- Migration, bending, fracture or loosening of the implant.
- Metal sensitivity, or allergic reaction to a foreign body.
- Decrease in bone density due to stress shielding.
- Pain, discomfort, or abnormal sensation due to the presence of the device.
- Increased fibrous tissue response around the fracture site and/or the implant.
- Necrosis of bone.
- Inadequate healing.

Apart from these adverse effects there are always possible complications of any surgical procedure such as, but not limited to, infection, nerve damage, and pain which may not be related to the implant

6. Comparisons to predicate devices:

Device Name	**Twist off™ Screw**	**Aesculap Titanium Alloy Bone Screws**	**K3 Bone Screw System**	**Le forte System (Bone Screw)**
Device Classification Name	No Comment	Screw, Fixation, Bone 888.3030	Smooth or Threaded Bone Fixation Fastener	Screw, Fixation, Bone 888.3040
Applicant	Medinov-AMP	Aesculp, Inc.	KMI (Kinetikos Medical Inc.)	Jeil Medical Corporation
510(K) Number	K971069	K970549	K960533	(This submission)
Material	Titanium Alloy	Titanium Alloy	Titanium Alloy (Ti-6Al-4V ELI Alloy : ASTM F136-84)	Titanium Alloy (ASTM F 136-98)
Intended use	Fixation of fracture, fusion of a joint or Bone	Long & small bone fracture fixation	Fixation/stabilization of small bones in hand or small bones in mid & forefoot	Small bone and mandibulofacial (mandible & Maxilla) fracture fixation

	reconstruction of the carpals, metacarpals & phalanges of the hand		fractures	reconstruction & stabilization of small bone and mandibulofacial (mandible & Maxilla)
Supplied Sterile?	No Comment	No Comment	No comment	Non sterile, steam sterilize before use

7. Conclusion: In all respects, the Leforte System Bone Screws are the equivalent of currently marked devices. They are made of the same materials and have similar dimensions and characteristics. Potential adverse effects are identical to those of predicate devices. This device is manufactured from material of titanium alloy (ASTM 136-97) that is used generally in this kind of bone screw. Similar devices made from titanium alloy (ASTM 136-97) to this device are manufactured and sold around the world. This device, Le forte system bone screw is substantially equivalent in design, material, intended use and function to the products on the table above. These devices are certificated by notified body for CE.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2003

Jeil Medical Corporation
c/o Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K023365
Trade Name: LeForte System Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: February 3, 2003
Received: February 4, 2003

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number K023365

Device Name: LeForte System Screws (various models)

"The Leforte System Screws are intended for fracture fixation as well as reconstruction and stabilization of small bones (i.e. toe, foot, finger, hand, etc) and the mandibulofacial (i.e. mandible and maxilla) bones."

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ OR Over the Counter Use_____
(Per 21 CFR 801.109)

for Mark N Milkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023365